

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION**

UNITED STATES OF AMERICA <i>ex rel.</i>)	
JEFFREY H. LIEBMAN and DAVID M.)	
STERN, M.D.,)	Case No.: 3:17-cv-00902
)	
Plaintiff-Relators,)	District Judge William L.
)	Campbell, Jr.
v.)	
)	Magistrate Judge Barbara D.
METHODIST LE BONHEUR HEALTHCARE)	Holmes
and METHODIST HEALTHCARE-MEMPHIS)	
HOSPITALS,)	
)	
Defendants.)	

**METHODIST’S RESPONSE TO UNITED STATES’
MOTION TO EXCLUDE EVIDENCE OF SAFE HARBORS**

Defendants Methodist Le Bonheur Healthcare and Methodist Healthcare-Memphis Hospitals (collectively, “Methodist”) file this response in opposition to the government’s Motion to Exclude Methodist From Introducing Evidence of an Unasserted Safe Harbor Affirmative Defense. (Dkt. No. 307.)

PRELIMINARY STATEMENT

The parties agree that Methodist has not pled any safe harbor to the Anti-Kickback Statute (“AKS”) as an affirmative defense in this action. Yet, as discovery comes to a close and summary judgment looms, the government moves to prevent Methodist from using sweeping categories of unidentified evidence under the guise that the evidence relates to an unasserted safe harbor defense. The government accuses Methodist of making “a backdoor assertion of an unasserted affirmative defense,” (Dkt. No. 310 at 2), but it is the government who is placing premature, vague, and irrelevant questions about AKS safe harbors before the Court. The government moves to exclude Methodist “from presenting any evidence regarding safe harbors to the [AKS],” (Dkt. No. 307

at 1), specifically referencing “evidence regarding the existence of exceptions to the [AKS],” “evidence that the agreements at issue satisfy individual elements of the personal services safe harbor,” “guidance or statements relating to the personal services harbor made after the time period of the conduct at issue,” and “evidence relating to the safe harbor” generally without ever identifying what evidence it is really seeking to exclude with such a broad request. (Dkt. No. 310 at 1–2.)

The government’s motion *in limine* should be denied because it is premature, insufficiently specific and, if taken at face value, seeks to exclude broad categories of relevant evidence. If the government seeks to prevent Methodist from uttering the words “safe harbor,” it does not specifically state this in its motion and, in any event, Methodist has not sought to put on evidence of a safe harbor that it has not asserted as an affirmative defense. If, instead, the government seeks to prohibit Methodist from presenting as evidence facts that overlap with elements of a safe harbor, including the safe harbor at 42 C.F.R. § 1001.952(d) (“Personal Services Safe Harbor”), that would foreclose Methodist from offering relevant, admissible evidence. For example, prior and current versions of the Personal Services Safe Harbor require that the personal services contract be set in writing signed by the parties and have a term not less than one year. *Id.* Does the government seek to prohibit Methodist from submitting evidence of its affiliation agreements with West, because they were writings signed by the parties with a term of seven years? That is an absurd result. The Personal Services Safe Harbor also requires, among other things, that compensation under an agreement be consistent with fair market value. *Id.* Does the government seek to prohibit Methodist from putting on evidence that its payments to West were consistent with fair market value and thus not unlawful remuneration under the AKS? The government’s motion is a thinly

veiled attempt to seek a “backdoor” summary judgment ruling on substantive elements of its claims through a purported evidentiary ruling that has no basis in the law or federal rules.

Methodist is entitled to rebut the government’s case in chief by arguing that the government fails to satisfy its burden to prove an AKS violation, even if some of that evidence arguably would also be relevant to a safe harbor defense that has not been asserted. The government’s motion to exclude should be denied as premature, insufficiently specific in what evidence it seeks to exclude, and for seeking the exclusion of evidence directly relevant to multiple claims and defenses in this case.

BACKGROUND

I. Complaint in Intervention

The government filed its Complaint in Intervention (the “Complaint”) on April 11, 2022, after nearly five years of investigation and litigation of allegations raised by Relators Jeffrey Liebman and David Stern. The government seeks to hold Methodist liable for “hundreds of millions of dollars in damages to Medicare as a result of Defendants’ violations of the Anti-Kickback Statute (‘AKS’) and the [False Claims Act].” (Dkt. No. 235 ¶ 1.) The government alleges that Congress “enacted safe harbors that protected certain prohibited payment and business arrangements that could otherwise implicate the AKS,” but that “safe harbors are affirmative defenses that are inapplicable here.” (*Id.* at ¶ 34.) Regarding Methodist’s contractual affiliation with West to operate Methodist’s oncology service line as West Cancer Center, the Complaint alleges that “the multi-agreement structure was a vehicle for kickbacks” and that “the complicated structure was designed so that physicians and hospitals could align in a manner that would avoid regulatory issues.” (*Id.* at 38 § II; ¶ 203 (heading style omitted).)

Specifically, the Complaint devotes more than 15 pages to allegations that the Management Services / Performance Improvement Agreement (“MSA”) under which West provided management services to Methodist’s oncology service line “cloaked Methodist’s unlawful payments to West.” (*Id.* at 39, § II(A); ¶¶ 204–84 (heading style omitted).) In summarizing the kickback scheme, the Complaint alleges that “[k]ickbacks for the revenues Methodist generated from the West referrals, however, were disguised as payments Methodist made during the deal, and expressly for certain services that were supposed to be—but were not—provided under the MSA.” (*Id.* ¶ 5.) Additionally, the Complaint characterizes the MSA as a “sham agreement” and alleges that Methodist knew that West provided “inaccurate and/or incomplete information to obtain the fair market valuation” for the agreement. (*Id.* at ¶¶ 284, 371.)

Likewise, in response to an interrogatory seeking identification of all unlawful remuneration that Methodist allegedly offered, paid, or received, the government stated, “The amounts Methodist paid to West under the MSA also constituted remuneration” because, *inter alia*, West did not pay its Medical Directors or Administrator from the base management fee as assumed in the fair market value opinion supporting the MSA. (Dkt. No. 296-1 at 7–8.) Additionally, the government asserts that Methodist double-paid West for services under the MSA and other affiliation agreements, constituting remuneration. (*Id.* at 8.) The government also asserts that Methodist paid West physicians “in excess of their professional collections over the time period 2012-2018” under the parties’ Professional Services Agreement, constituting another form of alleged remuneration. (*Id.* at 7.)

And, the government alleges that Methodist “*knowingly* agreed to pay West millions of dollars for the revenues Methodist expected to – and ultimately did – realize from West’s referrals” and “*knowingly* paid West remuneration through, at a minimum, the payments under the MSA for

a purpose of inducing West’s referrals of patients and ancillary services to Methodist[.]” (Dkt. No. 235 ¶¶ 10, 353) (emphasis added.) The government also makes allegations regarding “the parties’ true intentions” in forming the West Cancer Center and entering into the MSA, (*id.* ¶ 281), which it contends was “a means to disguise the fraudulent relationship.” (*Id.* at 54, § II(B) (heading style omitted).)

Methodist has denied these allegations. (Dkt. No. 242.) On summary judgment and at trial, Methodist is entitled to and will offer evidence that rebuts the government’s theories of remuneration and scienter, two elements of the AKS that the government bears the burden to prove.

II. Procedural Background and Methodist’s Requests for Admission

During discovery, Methodist served Requests for Admission on the government. Three of these requests sought admissions that: (1) the government has not identified rules, regulations, guidance, publications, education materials, or reports forbidding aspects of the West Cancer Center affiliation that the government contends were unlawful (Dkt. No. 271-6, RFA No. 4); (2) CMS and HHS have proposed rules seeking to promote flexibility and innovation in the delivery of more efficient and better coordinated care (*id.* at RFA No. 7); and (3) CMS and HHS have acknowledged a “compelling concern” that uncertainty and regulatory barriers could “prevent the best and most efficacious innovations from emerging and being tested in the marketplace.” (*Id.* at RFA No. 8.) The government refused to admit or deny these requests for admission, claiming that they were not relevant to any claim or defense in this action. The government also refused to admit or deny the requests on the grounds that it had not considered the issues in the requests and was under no obligation to do so. Because the government refused to admit or deny these RFAs (and refused to provide answers to numerous interrogatories or produce documents in response to

numerous document requests), Methodist filed a series of discovery motions seeking to compel responses. (Dkt. Nos. 260, 271, 273.)

On December 20, 2022, Magistrate Judge Holmes conducted a hearing on these discovery disputes. At the hearing, the Court indicated that it found that the government's responses to the requests at issue were insufficient under Rule 36(a)(4), but agreed to let the parties brief whether the RFAs were relevant. (Dkt. No. 299.) The Court instructed Methodist to file motions to deem the RFAs admitted and warned the government, "I think you're going to have a hard row to convince me . . . that it's not relevant. . . . But I will give you an opportunity to brief it as to relevancy. I'm simply cautioning you that I think there's going to be a very hard argument to make that this is not relevant in this case." (*Id.* at 81–82.)

With respect to RFA No. 4, Methodist explained that the government's failure to identify any publications or materials forbidding aspects of the West Cancer Center affiliation it contends are unlawful is directly relevant to whether claims for payment are "false" within the meaning of the FCA and whether Methodist "knowingly" submitted false claims. (Dkt. No. 302 at 4.) As to RFA Nos. 7 and 8, Methodist likewise explained that the admission sought is relevant to whether Methodist "willfully" violated the AKS and "knowingly" submitted false claims, as alleged by the government. (Dkt. No. 303 at 2–3.) Put differently, this information is relevant to Methodist's defense rebutting the government's case in chief on multiple elements of the AKS and FCA, irrespective of the Personal Services Safe Harbor. In response, the government argued that the requests are not relevant because they relate to safe harbors that Methodist has not asserted as an affirmative defense. (*See* Dkt. Nos. 305 at 4, 306 at 3–4.)

In an apparent attempt to circumvent Judge Holmes's likely-negative ruling, on January 13, 2023, at the same time that it filed the required briefing on the disputed requests for admission,

the government also filed this motion *in limine* seeking to preclude Methodist from “presenting evidence regarding the existence of exceptions to the [AKS], known as safe harbors . . . and specifically evidence identifying the elements of the personal services and management contracts (“personal services”) safe harbor in effect during the relevant time period, together with any amendments thereto, as well as evidence that Methodist should not be liable for any AKS violation because it has satisfied any individual element of the personal services safe harbor, and evidence relating to any guidance, advisory opinions or proposed rule changes concerning the personal services safe harbor” (Dkt. No. 310 at 1–2.) The government purported to “refer[] to and incorporate[]” its motion *in limine* into its five-page opposition briefs on the RFAs. (Dkt. Nos. 305 at 1, 306 at 1.)

On January 20, 2023, Judge Holmes deemed all disputed RFAs admitted. (Dkt. No. 312.) The Court rejected the government’s attempt to “assert[] that various claims or defenses are not at issue simply because the United States says so.” (*Id.* at 9.)¹ Specifically, as to RFA No. 4, Judge Holmes held that the information sought is “directly relevant to allegations made by the United States in the Complaint in Intervention and expanded on in discovery responses.” (*Id.* at 10.) As to RFA Nos. 7 and 8, Judge Holmes likewise held that the information sought is “directly relevant to issues in this case.” (*Id.* at 11.) Although Judge Holmes’s ruling concerns discoverability and the government’s obligations under Rule 36, the relevancy analysis nonetheless informs the instant consideration of the government’s motions *in limine*, which should be denied.

¹ Judge Holmes further stated, “Similar to the United States’ unilateral determination of the viability of claims and defenses, the United States’ qualifications to its answers that it is not under any obligation to consider the issues implicated by the requests are unilateral, self-serving, and improper determinations by a party of its obligations under Rule 36.” (Dkt. No. 312 at 9 n.4.)

ARGUMENT

“Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure authorize a court to rule on evidentiary motions *in limine*, but ‘the practice has developed pursuant to the district court’s inherent authority to manage the course of trials.’” *Thompson Rsch. Grp., LLC v. Winnebago Indus., Inc.*, 2021 WL 6750848, at *1 (M.D. Tenn. Feb. 11, 2021) (Campbell, J.) (quoting *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984)). The purpose of a motion *in limine* is to “narrow the evidentiary issues for trial and to eliminate unnecessary trial interruptions.” *Louzon v. Ford Motor Co.*, 718 F.3d 556, 561 (6th Cir. 2013). “Unless a party proves that the evidence is clearly inadmissible on all potential grounds – a demanding requirement – ‘evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context.’” *Thompson Rsch. Grp.*, 2021 WL 6750848, at *1 (quoting *In re Davol*, 505 F. Supp. 3d 770, 774 (S.D. Ohio)); *see also WEL Cos., Inc. v. Haldex Brake Prods. Corp.*, 467 F. Supp. 3d 545, 555 (S.D. Ohio 2020) (reasoning because courts can better determine the “value and utility of evidence” during the trial, “[t]o obtain the exclusion of evidence under such a motion, a party must prove that the evidence is clearly inadmissible on all potential grounds.”)

I. The United States’ Motion is Premature, Overbroad, and Insufficiently Specific.

“Courts ‘are generally reluctant to grant broad exclusions of evidence before trial because a court is almost always better situated during the actual trial to assess the value and utility of evidence.’” *Thompson Rsch. Grp.*, 2021 WL 6750848, at *1 (quoting *In re Davol, Prod. Liab. Litig.*, 505 F. Supp. 3d at 774); *see also Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975) (“Orders *in limine* which exclude broad categories of evidence should rarely be employed. A better practice is to deal with questions of admissibility of evidence as they arise.”)).

“Where a motion *in limine* simply asserts objections without tying them to specific evidentiary items, the Court properly may deny it as overbroad and insufficiently specific.” *Fakhoury v. O’Reilly*, 2022 WL 909347, at *6 (E.D. Mich. Mar. 28, 2022); *see also United States v. Frazier*, 443 F. Supp. 3d 885, 898 (M.D. Tenn. 2020) (“Even more fundamentally, the Government offers no specific concrete examples of any evidence it seeks to exclude. The Court will decline the Government’s invitation to rule in a factual vacuum.”); *Jackson v. O’Reilly Auto. Stores, Inc.*, 131 F. Supp. 3d 756, 760 (M.D. Tenn. 2015) (“Here, we are unable to resolve Plaintiff’s motion because he has not identified any particular piece of evidence that should be excluded. As a result, we cannot assess the likely relevancy or prejudice of the challenged evidence.”).

Here, the government seeks to prohibit Methodist “from presenting any evidence regarding safe harbors to the [AKS].” (Dkt. No. 307 at 1.) It is unclear whether the government is seeking to preclude explicit mention of the words “safe harbors,” or any and all facts in evidence that arguably overlap with elements of any safe harbor, or something in between, and the Court should deny the motion for lack of particularity.² There are more than three dozen enumerated safe harbors to the AKS. To grant the relief that the government seeks, the Court would have to consider whether each piece of evidence Methodist offers for summary judgment or at trial relates

² The nature and scope of the government’s motion could have been clarified before filing had the government made any meaningful attempt to confer with Methodist on the relief the government seeks. Methodist stated to the government that it was unable to take a position on the motions *in limine* for lack of clarity as to the relief sought, posing similar questions to the government as Methodist raises herein. (Dkt. No. 310-1.) Even now, it remains unclear precisely what evidence the government seeks to exclude, and the Court should not grant such a broad and undefined request, particularly at this stage. Methodist reserves the right to seek leave to submit a sur-reply to address any new arguments or requests for relief that the government may, improperly, attempt to make in reply.

to any one of those safe harbors. Granting that relief is completely unworkable and unsupported by the law or any rules of evidence or civil procedure.³

In *Jackson*, the plaintiff filed a motion *in limine* under Rules 402 and 403 to exclude broadly any evidence of his misconduct that was not a factor in defendant's termination of his employment, but he failed to identify particular evidence he argued should be excluded. 131 F. Supp. 3d at 759–60. In response, as here, the defendant argued that the motion lacked particularity and that the generalized evidence was relevant. *Id.* at 760. “Rather than issu[ing] a blanket ruling on evidence not yet identified and arguments not yet fully developed,” this Court denied the plaintiff's motion. *Id.*

It comes as no surprise that the government fails to identify any particular evidence that it seeks to exclude—the parties have not even submitted motions for summary judgment, and trial is still ten months away. Yet, the government now seeks to exclude broad swaths of unspecified and unasserted evidence, exemplifying why such motions are almost never granted and, if anything, are better reserved for trial. The Court should deny the motion.

II. The Evidence Is Relevant to Methodist's Defense, Irrespective of Any Safe Harbor.

Federal Rule of Evidence 402 provides “that evidence is admissible if it is ‘relevant.’” *United States v. Miller*, 2022 WL 17464479, at *1 (E.D. Ky. Dec. 6, 2022) (quoting *United States v. Dunn*, 805 F.2d 1275, 1281 (6th Cir. 1986)). Rule 401 defines “relevant evidence” as evidence that “has any tendency to make a fact more or less probable than it would be without the evidence,” and that “the fact is of consequence in determining the action.” Fed. R. Evid. 401. “This threshold

³ Indeed, the government's motion *in limine* is so broadly drafted that it would apply to types of evidence that the government itself almost certainly will seek to introduce, because the safe harbors relate to a wide variety of topics, ranging from space rental to personal services and management contracts to practitioner recruitment to electronic health records to reductions in price for prescription pharmaceuticals, among others.

is low, and evidence is relevant if it ‘advance[s] the ball’ one inch.” *United States v. Lang*, 717 F. App’x 523, 530 (6th Cir. 2017) (alteration in original) (quoting *Dortch v. Fowler*, 588 F.3d 396, 401 (6th Cir. 2009)) (reasoning that relevant evidence “casts some doubt” on the opponent’s “contention, which is all Rule 401 requires”).

In this lawsuit, the government alleges that Methodist’s financial arrangements with West violated the AKS, which prohibits the **knowing and willful** payment of **remuneration** that is **intended to induce** referrals. *See* 42 U.S.C. § 1320a-7b(b) (emphasis added). A claim is false under the FCA only if it “includes items or services **resulting from** a violation [of the AKS].” *Id.* § 1320a-7b(g) (emphasis added). The evidence which the government seeks to exclude is relevant to Methodist’s proof regarding these elements.

Notwithstanding the ambiguity in its motion as to exactly what evidence it seeks to exclude, given the broad strokes with which the government paints the contested hypothetical evidence, Methodist must take the government’s motion at face value that it seeks to exclude “any evidence regarding safe harbors” to the AKS. Such evidence is directly relevant to Methodist’s defense, because it can be offered to rebut or disprove the government’s theories in its case in chief as to elements of an AKS and FCA violation for which the government bears the burden of proof, even if it is not offered to establish a safe harbor. That Methodist has not raised a safe harbor affirmative defense does not change that analysis.⁴

⁴ The government is correct that the Sixth Circuit has not specifically held that AKS safe harbors are affirmative defenses. (*See* Dkt. No. 310 at 9.) For the purposes of the government’s motion *in limine*, Methodist assumes, *arguendo*, that they would be treated as such. However, for the reasons explained herein, evidence relating to safe harbors or elements thereof are relevant to Methodist’s defenses regardless of whether the Court treats the safe harbors as affirmative defenses or a part of the government’s *prima facie* case.

The government would task the Court with a near-impossible line-drawing exercise as to whether certain evidence Methodist may put forward relates to any one of more than three dozen unasserted safe harbors or merely a rebuttal of the prosecution's case—particularly where the evidence could, and almost certainly will, often relate to both. As one district court aptly explained:

Presentation of evidence on the safe harbor's affirmative defense may well also go to a failure to show the necessary elements of the offense. A ruling granting the government's motion would require to [sic] the Court to draw impossibly fine distinctions between safe harbor evidence and permissible attacks on the government's case in chief. The Court is unwilling to risk so limiting Defendant's case

United States v. Ekwebelem, 2014 WL 12633529, at *2 (C.D. Cal. Sept. 9, 2014) (denying the government's motion *in limine* to exclude the defendant's reference to an AKS safe harbor). In *Ekwebelem*, the district court found that the prosecution's motion *in limine* seeking to bar the defendant from referencing evidence that might be relevant to an AKS safe harbor went too far, and that the court would “not issue what amounts to a summary judgment ruling . . . especially in light of the very close connection between the elements of the offense and the facts necessary to establish the affirmative defense.” *Id.*

The government's reliance on *United States v. Trumbo*, 2019 WL 3289848 (E.D. Mich. July 22, 2019), is overstated. There, a district court held that a criminal defendant who was not raising a safe harbor as an affirmative defense to prosecution under the AKS could not “refer to the safe harbor provisions *as a defense to his case* or *as an ‘available’ defense* to anyone charged under the Statute.” *Id.* at *2 (emphasis added). Methodist is not asserting that the safe harbor itself is a defense to its case, nor is Methodist seeking to generally hold out the safe harbor as something entities may voluntarily avail themselves of in making a business arrangement and later raise as a defense should they be prosecuted. Further, the *Trumbo* court did not hold, as the

government seeks here, that a defendant is precluded from presenting evidence to rebut the government's case in chief if that evidence also relates to an element of some safe harbor(s). As explained previously in its motions related to the disputed requests for admission—which Judge Holmes has since ruled were relevant under Rule 26—evidence that is also related to safe harbors is relevant to Methodist's defense that the government is unable to prove elements of its claims.

First, “An AKS violation [] requires that there be ‘remuneration’ offered or paid in the transaction at issue.” *See Bingham v. HCA, Inc.*, 783 F. App'x 868, 873 (11th Cir. 2019). The Medicare Act broadly defines “remuneration” as “transfers of items or services for free or *for other than fair market value*,” 42 U.S.C. § 1320a-7a(i)(6) (emphasis added), and as appellate courts have ruled, this definition of remuneration shows that fair market value transactions do not breach the AKS. *Bingham*, 783 F. App'x at 873–75; *see also Miller v. Abbott Lab'ys*, 648 F. App'x 555, 561 (6th Cir. 2016) (quoting statute); *Jones-McNamara v. Holzer Health Sys.*, 630 F. App'x 394, 400 (6th Cir. 2015) (same). Methodist is entitled to put on evidence showing that its payments to West under the affiliation agreements were consistent with fair market value and that the government fails to prove there was remuneration under the AKS.

Second, in order for a claim to be “false” under the FCA, it must be inconsistent with a controlling rule, regulation, or standard authorizing it. *See, e.g., United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 674–75 (5th Cir. 2003). Methodist is thus entitled to put on evidence of the government's failure to identify any rules or other publications forbidding aspects of the West Cancer Center relationship in order to rebut the government's proof of falsity.

Third, the government also carries the burden of proving that Methodist “knowingly” and “willfully” acted in violation of the AKS, which requires a showing that Methodist “specifically intend[ed] to do something the law forbids, purposely intending to violate the law.” *United States*

v. McClatchey, 217 F.3d 823, 829 (10th Cir. 2000). The government has alleged that Methodist’s true intent in affiliating with West was to induce referrals. Methodist is entitled to put on competing evidence of its true intent, which was to promote efficient, better coordinated, innovative care—exactly as CMS and HHS have encouraged healthcare providers to do through proposed amendments to AKS safe harbors. That the government itself has encouraged the conduct Methodist undertook tends to show that Methodist’s true intent was consistent with government goals, not fraud. *Cf.* Order Under Seal at 33, *United States v. Holland*, No. 1:17-cr-0234 (N.D. Ga. Nov. 17, 2022) (previously filed at Dkt. No. 301-1) (“Defendants are also entirely correct in arguing that, while the Government repeatedly states that the contracts between [the hospital] and [the clinic] were pretextual, they have not presented any evidence to support that assertion or that Defendants believed the contracts were not legitimate.”). And, a defendant does not “knowingly” submit a false claim under the FCA when it acts within a reasonable interpretation of an ambiguous law, and there is no official guidance to warn the defendant away from that interpretation. *See, e.g., U.S. ex rel. Olhausen v. Arriva Med., LLC*, 2022 WL 1203023, at *2 (11th Cir. Apr. 22, 2022).⁵ Again, Methodist is entitled to put on evidence that the government has not identified rules or other publications forbidding aspects of the West Cancer Center relationship that the government alleges were improper in order to rebut the government’s proof of scienter.

Even though Methodist is not asserting a safe harbor affirmative defense, evidence related to and overlapping with the AKS safe harbors is still directly relevant under Rule 401 to

⁵ *See also U.S. ex rel. Proctor v. Safeway, Inc.*, 30 F. 4th 649, 652–53 (7th Cir. 2022); *United States v. Allergan, Inc.*, 746 F. App’x 101, 109–10 (3d Cir. 2018); *U.S. ex rel. McGrath v. Microsemi Corp.*, 690 F. App’x 551, 552 (9th Cir. 2017); *U.S. ex rel. Donegan v. Anesthesia Assocs. of Kan. City, PC*, 833 F.3d 874, 880 (8th Cir. 2016); *U.S. ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 289 (D.C. Cir. 2015); *U.S. ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340, 343–44 (4th Cir. 2022), *vacated and judgment aff’d by equally divided court*, 49 F.4th 873 (4th Cir. 2022).

Methodist's defense attacking the government's lack of proof on multiple elements of its case in chief. The government's motion *in limine* should be denied.

III. The Relevant Evidence Will Not Confuse the Court or a Jury.

Under Rule 403 of the Federal Rules of Evidence, courts “may exclude relevant evidence if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, [or] misleading the jury[.]” Fed. R. Evid. 403; *see also United States v. James*, 2007 WL 2174650, at *2 (W.D. Ky. July 26, 2007) (permitting criminal defendant to present evidence of mistaken interpretation of the AKS to negate willfulness element, finding it would not be unduly confusing to a jury to hear evidence on two interpretations of the law). This balancing “test is strongly weighted toward admission.” *United States v. Asher*, 910 F. 3d 854, 860 (6th Cir. 2018); *see also United States v. Florence*, 2021 WL 5567001, at *1 (M.D. Tenn. Nov. 29, 2021) (quoting *Asher* and declining to exclude evidence before trial). Courts consider the challenged evidence in the light most favorable to its proponent and only exclude evidence under Rule 403 that suggests a decision “on an improper basis.” *United States v. Poulsen*, 655 F.3d 492, 509 (6th Cir. 2011) (quoting *United States v. Newsom*, 452 F.3d 593, 603 (6th Cir. 2006)); *see also United States v. Scarborough*, 2015 WL 1579585, at *3–4 (M.D. Tenn. Apr. 9, 2015) (concluding it would not confuse or mislead the jury to let witnesses use certain language to describe their subjective understandings, and any confusion would be minimized by cross examination and jury instructions).

The government argues, “If Methodist is allowed to present evidence relating to the safe harbors, including the elements of the personal services safe harbor, it will not [sic] be more prejudicial than probative of any issue in this case.”⁶ (Dkt. No. 310 at 11.) The government

⁶ Presumably the government meant to say such evidence *will* be more prejudicial than probative or that the evidence will not be more probative than prejudicial. In any event, the standard under

speculates as to the multitude of ways in which a jury would be incapable of understanding the nuance between an unasserted affirmative defense and the ways in which components of safe harbors are simultaneously relevant to Methodist's attack on the government's case in chief. (*Id.*) Methodist does not so underestimate a jury, particularly where an appropriate instruction can be given, and the government offers no credible explanation as to why a jury instruction will not suffice to protect against confusion or decision on an improper basis. More immediately, Methodist does not so underestimate the Court, which first will review the evidence at summary judgment.⁷ Finally, determining whether evidence will confuse the jury, or is substantially more prejudicial than probative, is impossible where the government does not even identify in its motion what actual, specific evidence it seeks to exclude.

CONCLUSION

For the reasons stated above, the Court should deny the government's Motion to Exclude Methodist From Introducing Evidence of an Unasserted Safe Harbor Affirmative Defense. (Dkt.

Rule 403 requires that the probative value of evidence be *substantially* outweighed by a danger of prejudice or confusion, which requires more than a mere balancing of the scales. *Crowley v. Anderson Cnty.*, 2021 WL 5304194, at *3 (E.D. Tenn. Apr. 21, 2021) (“[F]or evidence to be excludable under Rule 403, the risk of confusion or prejudice must ‘substantially outweigh’ any probative value. The mere presence of such a risk is not enough.” (internal citation omitted)).

⁷ If the government is indeed seeking to prevent Methodist from putting forth any evidence that overlaps with an element of a safe harbor, such as the fair market value of the compensation Methodist paid West, it seems clear that this motion is not truly to protect the jury from confusing evidence, but rather is intended to get an out-of-context, preliminary ruling on legal issues likely to be raised at summary judgment. The government has been teasing a “very quick summary judgment motion on a discrete legal issue as to whether remuneration is—whether fair market value comes into play in determining remuneration” since it moved to intervene. (Dkt. No. 234 at 62:21–24.) Rule 56 provides a mechanism for objecting to the admissibility of evidence cited in support of, or to dispute, a fact at summary judgment. Fed. R. Civ. P. 56(c)(2). The Court need not take up this issue under the guise of a motion *in limine* weeks before summary judgment motions are to be filed. *See Louzon*, 718 F. 3d at 563 (“Where, as here, the motion *in limine* is no more than a rephrased summary-judgment motion, the motion should not be considered.”).

No. 307.) The motion is premature because it seeks to make an end-run around the Court's prior discovery rulings and asks the Court to make what is essentially a substantive ruling about the government's burden of proof and Methodist's ability to rebut that proof prior to summary judgment, much less trial. The motion is overbroad in its failure to specifically, or even cogently, identify the evidence that it seeks to exclude. And, the type of evidence at issue is directly relevant to Methodist's defenses irrespective of any unasserted affirmative defense and will not confuse the Court or the jury.

Dated: January 27, 2023.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and exact copy of the foregoing has been served on the following counsel via the Court's CM/ECF email notification system on this the 27th day of January, 2023:

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